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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/579,165	KEENAN, JAMES	
	Examiner	Art Unit	
	DAVID NAFF	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/17/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A preliminary amendment of 5/12/06 canceled claims 1-55, and added new claims 56-84.

Claims examined on the merits are 56-84, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 1 of claim 56 and where recited in other claims "circulating cells or foreign substances" is unclear as to phenomena that constitutes circulating cells or foreign substances since the environment in which circulating is occurring has not been specified. Additionally, the relationship of the circulating cells or foreign substances to the body vessel is unclear. Are the cells or foreign substances in the vessel or some other place? Substances that are foreign substances is further unclear since a substance being foreign is relative and subjective, and depends on individual interpretation.

In line 3 of claim 56 and where recited in other claims "body vessel" is uncertain as to meaning and scope. Is this a vessel attached to the body, inserted in a body or a blood vessel contained by the body? If the kind of body vessel is not known, one cannot know the configuration of a frame positioned in the vessel.

In line 3 of claim 56 and where recited in other claims "localized position" is uncertain as to meaning and scope. The difference in a position that is localized and not localized is uncertain. It is suggested "localized" be deleted.

In claim 58, line 2, "cell lining a fluid vessel" is uncertain as to meaning, and there is not antecedent basis for a cell lining a fluid vessel. Claim 56 requires circulating cells, and the relationship of the cell lining a fluid vessel to the circulating cells is unclear. If cells are circulating, how can a cell be lining a fluid vessel. Additionally, the claim is

unclear how the fluid vessel differs from the vessel in claim 56, and how "fluid" defines the vessel. Furthermore, claim 56 does not require cells since foreign substances are alternative to cells in claim 56.

Claim 60 is unclear how the device of claim 56 can contain cells or tissue as required when the device functions as required in claim 56 for attracting cells or foreign substances. The function of cells and tissue required in claim 60 is unclear in regard to attracting as required by claim 56. In the last two lines of claim 60, substances that are a "biotherapeutic" or "chemical" is unclear since the function of these substance relative to the circulating cells and attractant in claim 56 not specified.

Claim 61 is unclear as to the meaning and scope of "shaped and/or coated to mimic the physiology of body organs". Being a mimic of a body organ is relative and subjective and depends on individual interpretation.

Claim 62 is unclear as to modification that will enhance visibility to imaging systems as required since conditions for using the imaging systems have not been required.

Claim 63 is unclear as to a foreign chemical substance that functions as an attractant since material the chemical substance is foreign to is not specified, and this foreign substance has not been distinguished from the foreign substance in claim 56. The claim is further unclear as to a substance that is a protective and extends release since properties of the substance are not specified other than being protective and extending release.

Claim 66 is unclear how the device of claim 56 can have the structure of claim 66. The relationship of the container for containing or dispensing the attractant in claim 66 to the frame configured as in claim 56 is unclear. Claim 66 is not further limiting the device of claim 56, but is requiring a different device. The device having a container as required by claim 66 cannot be configured for attachment in a body vessel as required for the device of claim 56. This also applies to claim 67, since it is not seen how the device of claim 56 can be configured as required when containing the container of claim 66 and the replenisher of claim 67.

In line 2 of claim 66, "said containment means" does not have antecedent basis.

Claim 68 is unclear where the device of claim 56 contains the therapeutic agent relative to the attractant required by claim 56.

Claims 69-71 are unclear how a "mechanical agent" (line 3 of claim 69) can function as a therapeutic agent as part of the device configured as required by claim 56. Claims 70 and 71 are unclear as to structure of a mechanical agent that functions as required in the claims when part of a device configured as required in claim 56. How such mechanical agents can fit in a body vessel when part of a device having a frame as required by claim 56 is unclear.

Reciting "preferably" in line 2 of claim 72 makes the metes and bounds defined by the claim unclear since the preferred components are not patentably limiting. Additionally, the claim is unclear as to a therapeutic agent that is a foreign substance in line 3 since material the substance is foreign to is not specified, and the difference in this foreign substance to that in line 1 of claim 56 is not made clear.

Claim 73 is unclear how a ferrous particle can function as a therapeutic agent. Such particles are not normally known to be therapeutic.

Claims 74 and 75 are confusing and unclear for the same type of reasons as claims 66 and 67. Claims 66 and 74 are changing the structure of the device of claim 56 so it is incapable of attachment to a position in a body vessel as required by claim 56.

Method claim 76 is confusing and unclear as to the method performed since method steps are not recited. Additionally, it is not seen how a method using a cellular attractant, viral attractant and treatment of cancer together can be performed by reciting "and/or".

Method claim 77 is confusing and unclear by failing to set forth clear, distinct and positive method steps consistent with functioning of the device of claim 56 as required in claim 56. In line 3, claim 77 is unclear as to steps that constitute "systemic chemotherapy treatment". In lines 4 and 5, claim 77 is unclear whether deploying of the device is in a body vessel as required by claim 56. Lines 4 and 5 are unclear where the diseased cells are circulating in the body. In lines 6 and 7, the claim is unclear where the white blood cells are introduced into the body.

Claim 78 is confusing and unclear for the same type of reasons as claim 56. The claim is further unclear by requiring attracting cells or foreign substances in line 1, and in line 6 requiring attracting a diseased cell or virus,

which is inconsistent with attracting as in line 1. Additionally, whether the diseased cell or virus is circulating as required in line 1 is unclear.

Claim 79 is unclear for the same type of reasons as claim 56 where the same language occurs. Reciting "foreign substance" in claims 79-81 is unclear for reasons set forth above.

Claims 79-83 are unclear whether the attractant and therapeutic agent are provided in the body vessel proximate the frame which is deployed in a body vessel. If the attractant and therapeutic agent are not also in the body vessel, it is not seen how they can function outside the body vessel.

Claim 84 is unclear by requiring an implantable device according to claim 80 since claim 80 is drawn to a method. Furthermore, it is not seen how a therapeutic agent can include an external energy source when provided proximate the frame in a body vessel. Is the energy source also in the body vessel?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 56-61, 63, 64, 68-72, 75, 76, 78-82 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shepard (WO 03/061718) in view of Zetter et al (4,732,155) and Lemelson (5,865,744) and Vicari et al (WO 02/058723), and if needed Briesewitz et al (6,272,712).

The claims are drawn to an implantable device for attracting circulating cells or foreign substances comprising a frame containing an attractant capable of attracting a disease cell or foreign substance. Also claimed is a method of attracting circulating cells and foreign substances.

Shepard discloses using enzyme attached to a device such as a stent to act on a substrate in blood to produce a therapeutically effective molecule such as cortisone. For example, see paragraphs 0022 and 0042-0046.

Zetter et al disclose a system containing a chemoattractant for attracting cells to a matrix that traps the cells. The cells are examined and characterized. For example, see col 2, line 40 to col 3, line 51).

Vicari et al disclose modulating the immune response by using chemokines to attract dentritic cells to a site of antigen delivery (page 5, line 5 to page 6, line 16).

Lemelson discloses (col 19, lines 53-60) a drug comprising nucleotides in a particulate carrier conjugated to a monoclonal antibody having a specific binding affinity for a targeted cell. After binding to the targeted cells, the drug is internalized into the cell by endocytosis.

Briesewitz et al disclose a bifunctional molecule containing a drug and a presenter protein ligand that targets the drug to a disease cell (abstract).

It would have been obvious to replace the enzyme of Shepard with a chemoattractant as disclosed by Zetter et al or a chemokine as disclosed by Vicari et al to attract cells for targeting a therapeutic agent as disclosed by Lemelson since this would have been expected to provide a therapeutic affect desired by Shepard and would have been expected to be beneficial in permitting the use of a drug therapeutic agent for targeting a cell as suggested by Lemelson, and if needed Briesewitz et al. The method of claims 78-82 would have been an obvious method of attracting disease cells for the same type of reasons for producing the implant.

Claim Rejections - 35 USC § 103

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 56-61, 63, 64, 68-72, 75, 76, 78-82 and 84 above, and further in view of Parker et al (6,306,125).

The claim requires enhancing the visibility of the device to imaging systems.

Parker et al disclose enhancing visibility of an implant to imaging systems (col 9, lines 6-10).

When using an implantable device containing an attractant for attracting cells and targeting a therapeutic agent to the cells as set forth above, it would have been obvious to enhance visibility of the device to an imaging system as suggested by Parker et al to enable using an imaging system.

Claim Rejections - 35 USC § 103

Claims 65 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 56-61, 63, 64, 68-72, 75, 76, 78-82 and 84 above, and further in view of Handy et al (WO 03/022360).

The claim requires the attractant to include a ferrous particle.

Handy et al disclose treating a disease by administering a therapeutic composition containing magnetic particles attached to a target-specific ligand and applying an alternating magnetic field to heat the composition. For example, see the abstract.

When using an implantable device containing an attractant for attracting cells and targeting a therapeutic agent to the cells as set forth above, it would have been obvious to include a ferrous particle with the attractant to permit the use of a magnetic field as disclosed by Handy et al.

Claim Rejections - 35 USC § 103

Claims 66, 67 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 56-61, 63, 64, 68-72, 75, 76, 78-82 and 84 above, and further in view of Jan ten Cate (6,352,683).

The claims require an external ultrasonic energy source for dispensing the attractant.

Jan ten Cate discloses release of a drug from a carrier material using ultrasonic energy (abstract).

When using an implantable device containing an attractant for attracting cells and targeting a therapeutic agent to the cells as set forth above, it would have been obvious to use ultrasonic energy to dispense the attractant as suggested by Jan ten Cate.

Claim Rejections - 35 USC § 103

Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 56-61, 63, 64, 68-72, 75, 76, 78-82 and 84 above, and further in view of Pomato et al (5,578,289).

The claim requires the therapeutic agent to be an ionizing radiation source.

Pomato et al disclose (col 1, lines 9-20) using ionizing radiation for cell destruction.

When using an implantable device containing an attractant for attracting cells and targeting a therapeutic agent to the cells as set forth above, it would have been obvious to use ionizing radiation as a therapeutic agent as suggested by Pomato et al.

Claim Rejections - 35 USC § 103

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 56-61, 63, 64, 68-72, 75, 76, 78-82 and 84 above, and further in view of Babb (4,381,004) and Bender et al (5,700,691).

The claim requires removing white blood cells from a body, providing a systemic chemotherapy to the body, capturing diseased cells with the device, and reintroducing the white blood cells to the body for degrading the diseased cells.

Babb disclose extracorporeal treatment of blood by withdrawing blood from a body, treating the blood with a microorganism inactivator, removing the inactivator, and returning the blood to the body (abstract).

Bender et al disclose that the main disease-fighting cell of the human immune system is the white blood cell (1, lines 16-25).

When using an implantable device containing an attractant for attracting cells and targeting a therapeutic agent to the cells as set forth above, it would have been obvious to use the device to capture diseased cells and not capture white blood cells by separating white blood cells, capturing the diseased cells and using the white blood cells to degrade the diseased cells as suggested by the extracorporeal method of Babb and the function of white blood cells disclosed by Bender et al. The inactivator used by Bender et al is a chemotherapy treatment, and it would have

been obvious to use this treatment for inactivating pathogenic microorganisms before capturing diseased cells to prevent the microorganisms from being captured with the diseased cells.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID NAFF whose telephone number is (571)272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit 1657

DMN
4/21/11